

SECTION X

**DEVICES CURRENTLY/PREVIOUSLY
AVAILABLE**

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A. General Availability

Metal/metal constrained, and semi-constrained total hip prostheses have been generally available throughout the U.S. and Europe since the 1950's. These were the first (and only) devices that were available to orthopaedic surgeons since the advent of hip replacement arthroplasty. With the introduction of low friction arthroplasty (LFA) by Sir John Charnley in 1960's, the use of metal/metal articulations for total hip prostheses fell into disfavor, more so in the U.S. than Europe. Use of metal/metal hip prostheses had virtually ceased in the U.S. by the time the Food and Drug Administration's Orthopaedic Device Section of the Surgical and Rehabilitation Devices Panel published its Final Rule on September 4, 1987 which placed these devices into class III. While use of metal/metal hip designs diminished in favor of metal/polyethylene designs in Europe, their use was not discontinued, and, in fact, they are enjoying a renewed interest as an alternative to the conventional metal/polyethylene total hip prostheses.

B. Currently Available Metal/Metal Hip Prostheses

Since August 1999, there are three commercially available metal/metal semi-constrained total hip prostheses

1. Sulzer Orthopedics, Inc.
Inter-Op™ Metasul® Acetabular System
K974728, August 3, 1999
2. Sulzer Orthopedics, Inc.
APR® Metasul® Acetabular System
K993569, December 1, 1999
3. Biomet, Inc.
Biomet Metal-On-Metal Acetabular System
K993438, May 18, 2000
4. Biomet, Inc.
M2a Ringloc Acetabular Liner
K002379, August 31, 2000
5. DePuy, Inc. a Johnson & Johnson Company
Ultima® Metal on Metal Acetabular Cup
K001523, August 10, 2000

C. Previously Available Metal/Metal Hip Prostheses

All of the following metal/metal hip prostheses were distributed in the U.S. prior to the enactment of the Medical Device Amendments to the U.S. Food, Drug and Cosmetic Act; therefore, these devices were not regulated.

Semi-constrained Metal/Metal Total Hip Prostheses:

1. Zimmer, USA and OEC, Inc.
McKee-Farrar Hip Prosthesis
Preamendments Device
2. Zimmer USA and OEC, Inc.
Sbarbaro Total Hip Prosthesis
Preamendments Device
3. OEC, Inc.
McBride Type Total Hip Prosthesis
Preamendments Device

Constrained Metal/Metal Total Hip Prostheses:

1. United States Surgical Corp
Sivash Total Hip Prosthesis
Preamendments Device